



PARTNER SOLUTIONS EXCELLENCE



Trusted Expertise ...

Delivered

How does our name define what we do?

We understand that relationships matter. As your strategic **PARTNER**, we share your passion for supplying lifesaving medicines to patients around the world. To achieve success, we are fully committed to your client experience as your partner, bringing together exceptional people with the knowledge and experience to understand the challenges facing your development, manufacturing, and commercialization of drug products.

Working collaboratively with you, we seek innovative **SOLUTIONS** to your most pressing challenges. We believe that active and timely communication during all stages of each engagement is a cornerstone to achieving success and earning your trust. Our initial project evaluation is highly collaborative to understand your priorities, critical performance attributes, and perspective of the issues to be addressed. We translate this comprehension into an actionable, fit-for-purpose strategy to execute each milestone within the agreed upon timelines. As part of this planning, we identify the appropriate staff with the relevant experience and expertise, analytical techniques, optimal processes and methods, and pertinent technologies to deploy on your engagement, yielding possible strategic options, if needed, and, ultimately, assisting in selecting the proper innovations to address your needs. Leveraging an unwavering commitment to project planning and management, our professionals provide reliable support to you, monitoring project status continuously and working together across operational disciplines to anticipate and resolve strategic and technical risks identified during the project to make sure that your project is delivered on time and in full.

At Parsolex, we strive for **EXCELLENCE** in every aspect of our work. We are committed to a culture of producing the highest quality output, performing continuous improvement to maximize operational efficiency, and delivering consistent reliability. We combine state-of-the-art technologies with the experience and knowledge of our subject matter experts to provide you with confidence in achieving the best possible outcomes. While adopting industry best practices is not always easy, it has allowed us to maintain a consistent record of meeting the highest regulatory, safety, and quality standards from the lifecycle of a clinical development program to the manufacture of commercial product.

**Let us show you
how Trusted
Expertise is
Delivered.**

ABOUT US

Established in 2004, Parsolex is a world-class contract services company delivering analytical, development, manufacturing, and strategic advisory solutions to clients who are involved with non-sterile pharmaceutical products for clinical trials as well as commercialization. Our clients include leading academic institutions, major hospital systems, start-up's, virtual companies, and large multinational pharmaceutical companies from around the globe, and we offer the following solutions to our clients:

- ✕ Analytical
- ✕ Good Manufacturing Practices ("CGMP") Manufacturing
- ✕ Commercialization
- ✕ Product Development
- ✕ Strategic Advisory

WHY PARTNER WITH US

Parsolex strives for shared success. We succeed when our clients succeed, and our clients choose to partner with us for the following reasons:

QUALITY

Parsolex is dedicated to maintaining best practices in quality standards, leveraging advanced quality systems, to make sure that we are delivering the highest quality products and services. Due to our exemplary principles to adhere to regulatory compliance, we have not received any Form 483's from any U.S. FDA inspections since 2008.

CLIENT FOCUS

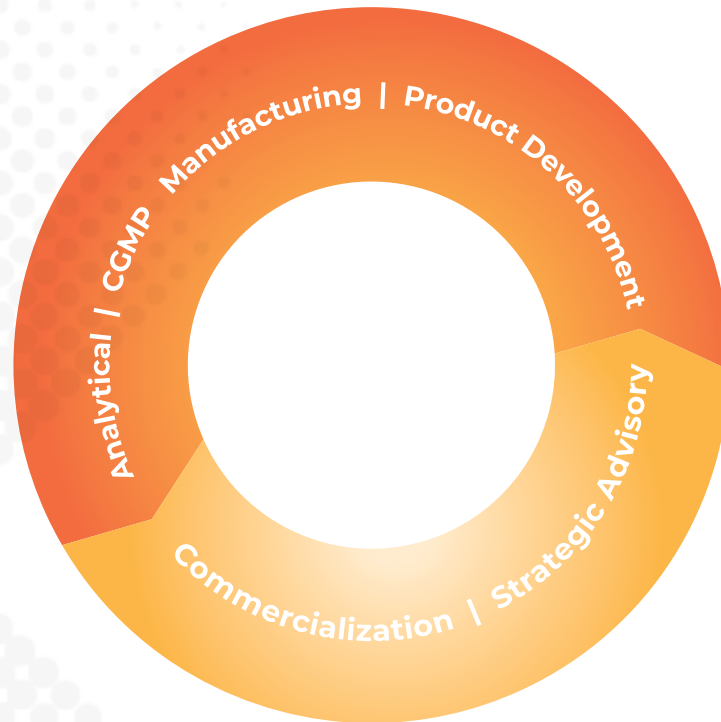
Parsolex is fully committed to developing deep relationships with our clients to understand their challenges and providing exceptional, collaborative experiences when we are engaged, fostering an environment of consistent and reliable performance by our professionals to solve such issues.

RESULTS

Parsolex combines multi-disciplinary teams and state-of-the-art capabilities to support innovation, solve formulation problems, tackle manufacturing challenges, improve operational efficiency, and address the production needs of our clients, whether for clinical trials or commercialization objectives, under fully CGMP-compliant procedures.

SOLUTIONS THAT WE PROVIDE

Parsorex has invested in bringing together experts and advanced analytical and manufacturing technologies to create a suite of technical and commercial solutions to offer our clients.



Technical



Commercial

TECHNICAL CAPABILITIES

Parsolex has built a state-of-the-art facility that houses analytical and manufacturing technologies and a team of pharmaceutical experts who have a demonstrated record of successful formulation design, process development, technology transfer, scale-up, manufacture and packaging for a broad range of oral solid dosage forms, including but not limited to tablets, film-coated tablets, and hard gelatin capsules filled with powder, granule and coated-beads. Parsolex has devised successful strategies for over-encapsulation of comparator products, and routinely delivers matching placebos to support clinical studies.

To meet the diverse needs of our clients, we have also produced other non-solid products such as semi-solids, syrups, and suspensions. Our technical solutions are supported by our analytical, product development, and CGMP manufacturing capabilities.

Our **Analytical Solutions** offer unparalleled support for product development, including method transfer, development, optimization, and validation, compendial testing of raw materials and active pharmaceutical ingredients (API), the qualification of raw materials, APIs, and excipients, product release testing, storage to support long-term ICH stability studies for drug products and drug substances, and cleaning verification development and validation.

Additionally, Parsolex can coordinate the following analytical methods for clients:

- ✂ Dissolution
- ✂ Fourier Transform Infrared Spectroscopy (FTIR)
- ✂ UV Spectroscopy
- ✂ High Performance Liquid Chromatography (HPLC) with Photodiode Array (PDA) Detection
- ✂ Thin Layer Chromatography
- ✂ Residue on Ignition
- ✂ Titrations
- ✂ Wet Chemistry Techniques

Our **Product Development Solutions** can meet the development needs of clients from pre-Phase I through small Phase III production as well as legacy drug commercialization:

- ✂ Pre-Formulation
- ✂ Clinical-Enabling Formulation Development
- ✂ Commercial Formulation Design
- ✂ Process Development & Scale-up
- ✂ Quality by Design (QbD)
- ✂ Process Analytical Technology (PAT)

Our **CGMP Manufacturing Solutions** are capable of executing a variety of processes that are supported by a range of technologies for operational efficiency:


- ✂ **Blending** Intermediate Bulk Containers ("IBC") for closed transfers and improved batch integrity
- ✂ **Granulation** Low shear, high shear, and fluid bed (spray) available depending on the physicochemical properties and desired performance attributes of the finished product
- ✂ **Drying** Tray (convection) or fluid bed available depending on the desired heat and mass transfer rates required during drying
- ✂ **Milling** Conical sieve wet and dry product mills to achieve the desired particle size distribution
- ✂ **Tablet Compression** Single station for prototype and small-scale production
Rotary for scale-up and full-scale production
- ✂ **Coating** Drum coating for cosmetic and functional film coating, including controlled release
Precise spray coatings on particles and beads
- ✂ **Encapsulation** Dosating nozzle type equipped with capsule weight checking for 100% verification
Over-encapsulation for blinding of comparators

COMMERCIAL CAPABILITIES

Parsolex acknowledges that our clients may face a number of commercial challenges, ranging from prioritizing a research & development pipeline, managing a product's lifecycle, to commercializing a brand or drug product. Our highly educated professionals have a diverse set of experiences, wealth of industry knowledge, and strong business acumen that can help in such situations.

Our **Strategic Advisory Solutions** provides our clients the ability to supplement their internal resources with our most valuable assets, our professionals. When experience and capabilities are required to provide answers to complex business questions, we partner with our clients to evaluate pharmaceutical research and development portfolios for investment potential, map product development strategies, and define investment opportunities for both new chemical entities and existing products as part of lifecycle management. Our clients will benefit from our experiences and "external" thinking, leveraging our experts, processes and templates, and other resources, to develop clarity on how to best proceed on these and other strategic topics that drive their profitability and shareholders' return.

Our **Commercial Solutions** allows our clients to benefit from leveraging our existing infrastructure to commercialize drug products. Parsolex has well-established expertise and capabilities in the commercial manufacturing of legacy and small-volume drugs. These successes have been achieved through the close coordination of development and production, which allows for seamless technology transfer during scale-up, transfers from other locations, process validation and routine manufacturing. We have been able to build upon these manufacturing successes to establish an infrastructure to commercialize drug products. For example, since 2007, Parsolex has maintained the supply of a small volume but medically necessary drug so that those North American patients who need the medication can get access to it. Our clients can access this established commercial foundation for the opportunity to generate revenues from their drug products.

A stylized, dark gray map of a road network is overlaid on a black background. A red location pin is placed on one of the roads, indicating the location of Parsolex. The map lines are of varying thickness, suggesting different road types.

Parsorex is located in West Lafayette, Indiana. Our main corporate office and manufacturing facility is situated in the technology-driven Purdue Research Park, just north of Purdue University's main campus. The Purdue Research Park is a major facilitator of commercialization and economic development in Indiana for both start-ups and established companies, and it is the home of several internationally known service providers to the pharmaceutical industry.

Contact Us

Purdue Research Park
3000 Kent Avenue, Suite C1-100
West Lafayette, IN 47906-1075

USA +1 765 464 8414
www.parsorexinc.com

info@parsorexinc.com

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